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VIA EFILING
The Hon. Kent A. Jordan
USDC for the District of Delaware
844 King Street
Wilmington, DE 19801

RE: ***Janssen Pharmaceutica N.V. et al. v. Mylan Pharmaceuticals et al.***
D. Del., C. A. No. 05-371 KAJ

Your Honor:

My firm, along with Rakoczy Molino Mazzochi Siwik LLP, represents Defendants Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. (collectively, "Mylan") in the above-captioned litigation. After Plaintiffs' counsel indicated that they would be submitting a statement in support of their discovery proposal, we prepared this letter in support of Defendants' discovery proposal, submitted to the Court on October 6, 2005. For the Court's convenience, we attach a chart summarizing the parties' respective positions and a copy of the patent-in-suit.

INTRODUCTION

Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. (collectively, "Plaintiffs") filed seven separate lawsuits against thirteen individual Defendants, alleging infringement of U.S. Patent No. 4,663,318 ("the '318 patent") against each Defendant (collectively, "the '318 Patent Litigation"). The '318 Patent Litigation arose after one Defendant in each action filed an abbreviated new drug application ("ANDA") seeking approval from the U.S. Food and Drug Administration ("FDA") to market a generic version of Janssen's brand-name drug Razadyne® (galantamine hydrobromide) prior to the '318 patent's expiration. Each Defendant's ANDA contained a "paragraph IV certification," indicating that it seeks immediate FDA approval because the '318 is invalid, unenforceable, and/or will not be infringed by the proposed ANDA products.

As this Court knows from its prior ANDA cases, time is of the essence in cases brought under Hatch-Waxman. This is, of course, why Congress imposed a statutory obligation on the

parties to ANDA litigation, such as the parties to the '318 Patent Litigation, to "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii). And, as explained below, time is even more critical in this case because the '318 patent expires on December 14, 2008.

DISCUSSION

Defendants' discovery proposal provides each of them a fair opportunity to pursue their defenses to Plaintiffs' infringement claims, and gives effect to the parties' statutory duty to expedite this litigation. Plaintiffs' proposal, on the other hand, seeks to limit each Defendant's right to take meaningful discovery within the confines of an unnecessarily long discovery period.

I. Each Defendant Should Be Permitted To Develop The Discovery Necessary To Defend Against Plaintiffs' Infringement Allegations.

Interrogatories (Section 4(c)). Plaintiffs sued thirteen individual Defendants, each of whom has a right to propound 25 interrogatories under the Federal Rules of Civil Procedure, while District of Delaware Local Rule 26.1 provides for 50 interrogatories. But Defendants do not seek the full discovery rights provided for them by these Rules. Rather, Defendants propose that related parties who are named as either plaintiffs or defendants be treated as a single party, and that each party get 25 interrogatories. Defendants' proposal ensures that they will have the opportunity to adequately defend against Plaintiffs' infringement allegations.

Departing dramatically from both the Federal Rules and the Local Rules of this Court, Plaintiffs want to limit *each side* to 50 interrogatories. Even if this number is divided by the number of lawsuits, instead of by the number of Defendants, this would allow Defendants in each case to propound *only 7* interrogatories during the entire course of the '318 Patent Litigation. Such an unreasonably low number severely prejudices the Defendants. Plaintiffs' caveat that "substantially similar" interrogatories propounded by more than one party would be treated as a single interrogatory, not only fails to fix the inequities of their proposal, but also creates an unworkable discovery process. The proposal, for example, invites significant, time-consuming disputes over whether particular interrogatories are "substantially similar."

Depositions (Section 4(a)). Defendants seek a reasonable number of hours of deposition testimony, as well as the right for each Defendant to adequately depose a few of the key witnesses. Specifically, Defendants request: that each side receive a total of 140 hours of deposition testimony; the right to question the inventor of the '318 patent for up to twenty-one hours; and that each side be allowed to depose up to two other witnesses for up to fourteen hours.

Seven different lead counsel represent the thirteen individual Defendants that Plaintiffs have sued. The Federal Rules provide that the "court must allow additional time consistent with Rule 26(b)(2) if needed for a fair examination of the deponent . . . ." FED. R. CIV. P. 30(d). For

each Defendant in the '318 Patent Litigation to obtain a "fair examination" of the inventor, additional time is necessary. Twenty-one hours gives each lead counsel three hours, which is appropriate given the importance of the inventor in a patent case. While the Defendants will make every effort to coordinate discovery, any Defendant who does not receive a "fair examination" of this key witness would be prejudiced. For this same reason, Defendants also seek the right to depose two additional witnesses for up to fourteen hours. Even though a single lead law firm represents all three Plaintiffs, Defendants' 14-hour proposal applies to Plaintiffs.

Plaintiffs seek an unreasonably large amount of deposition time and, at the same time, to restrict Defendants' ability to properly defend themselves against Plaintiffs' infringement allegations. This case involves a single, two-and-a-half page patent – a method-of-use patent – with only seven claims. The only information that Plaintiffs need regarding infringement is in the seven ANDAs at issue here. Consequently, the testimony required on infringement will be substantially limited in scope. Thus, Plaintiffs do not need 250 hours of deposition testimony. Plaintiffs also should not be permitted to refuse Defendants the time that they need to depose key witnesses. For the reasons discussed above, Defendants need additional time with the inventor and two other key witnesses.[1] Thus, Plaintiffs' attempt to limit Defendants to fourteen hours with just one witness also should be rejected.

Joinder and Pleading Amendments (Section 2). Defendants propose cutting off amendments to pleadings 30 days before the close of fact discovery. Doing so allows both sides time to review written discovery and conduct the depositions that often are necessary before a claim can be adequately pleaded. Inequitable conduct defenses, for example, must be pleaded with particularity under Rule 9 and, therefore, can require extensive investigation before being pleaded. Defendants' proposal makes such investigation possible. Plaintiffs' proposal, on the other hand, would deprive Defendants of this opportunity by having pleading amendments cut off *6 months* before the close of fact discovery.

II. Plaintiffs' Proposed Discovery Schedule Is Unreasonably Long.

Despite their statutory duty to cooperate in expediting this ANDA litigation, Plaintiffs propose an unreasonably long discovery schedule for this case, which involves *one* method-of-use patent having just seven claims. Plaintiffs brought suit against Mylan on June 6, 2005, and the other Defendants around that same date. Defendants seek a fact discovery closing date of June 16, 2006, just over a year into the litigation. That period provides both parties with

[1] Plaintiffs also seek to prevent any "person" from being deposed more than once without leave of the Court. If adopted, this restriction should apply only to persons being deposed in his or her individual capacity. If Plaintiffs, for example, offer a witness in response to a Rule 30(b)(6) notice, Defendants should not be prevented from later deposing that witness in his or her individual capacity.

sufficient time to complete fact discovery, so long as all parties comply with their statutory obligation to cooperate. Plaintiffs – whose sales of Razadyne® exceeded $4.5 million *per week* for the 12-month period ending August 2005, according to IMS Health data – seek a September 2006 discovery closing date. This is unnecessarily long, especially given the facts here:

- Mylan produced the relevant portions of its ANDA to Plaintiffs on May 20 and 26, 2005. In fact, as we understand it, Plaintiffs also received the relevant portions of nearly all of the seven ANDAs giving rise to the '318 Patent Litigation in May 2005.

- Since at least May 2005, Plaintiffs have known about the invalidity positions that Defendants have developed so far. Each Defendant provided Plaintiffs with a detailed explanation of its invalidity positions, including citation to prior art.

- Some Defendants already have provided Plaintiffs with their Rule 26(a)(1) disclosures, and started producing documents cited therein.

Plaintiffs have indicated that they would need third-party discovery from Novartis, another brand company located overseas. Even if Plaintiffs need this discovery, it does not warrant the long period that Plaintiffs seek. Depositions through the Hague Convention and letters rogatory can take place within the time provided by Defendants' proposal, particularly if Plaintiffs start the process now, as Defendants suggested to them weeks ago. Plaintiffs do not need fifteen months for fact discovery.

Plaintiffs also claim to need six months for expert discovery, while Defendants seek only four months. Six months is too long for a case involving one method-of-use of patent with only seven claims (not all of which may be asserted). The parties to this ANDA case can comfortably complete expert discovery in four months.

Finally, Plaintiffs seek a November 2007 trial date, while Defendants seek a March 2007 trial date. As Plaintiffs well know, the '318 patent expires in December 2008. A November 2007 trial date threatens to deprive Mylan (and other Defendants) of the incentive that Congress created to encourage challenges to suspect drug patents like the '318 patent. Specifically, Congress rewards the first company to file an ANDA challenging the validity, enforceability, or infringement of a listed patent with the right to market its generic product free from competition for 180 days. *See* 21 U.S.C. § 355(j)(5)(B)(iv). In this case, the only way that Mylan (and other Defendants) can enjoy the full benefit that Congress created, without running the risk of incurring liability for infringement damages, is if this Court rules in Defendants' favor by the end

of 2007 or early 2008.[2] Plaintiffs' November 2007 trial date would make this difficult, if not impossible. Defendants' March 2007 trial date should provide enough time for such a ruling.

III. Claim Construction (Sections 12 and 13).

On September 9, 2005, Defendants asked Plaintiffs to identify and construe the patent claims that they are asserting against Defendants. While Rule 11 required Plaintiffs to undertake this analysis as part of their pre-suit obligations, Plaintiffs refused to provide this information before submission of the scheduling order.[3] Consequently, Defendants had no way of knowing whether the parties dispute any claim terms. Defendants thus proposed a schedule that would permit any disputes to be resolved prior to the completion of expert reports. This way, the parties' experts necessarily would be addressing the correct issues in their reports.

IV. Plaintiffs' Discovery Proposal Strays From Well-Established Legal Authorities.

Willful Infringement (Section 3). Plaintiffs have asserted a claim for willful infringement against each Defendant. Such claims are defective as a matter of law. Defendants asked Plaintiffs to voluntarily withdraw these claims in light of controlling Federal Circuit case law, as well as cases from this District. Plaintiffs refused. Thus, Mylan will seek to dismiss or strike Plaintiffs' willful infringement claim, the precise relief that Judge Sleet recently granted in a case involving a "paper NDA." *See Allergan, Inc. v. Alcon, Inc.*, No. 04-0968 (D. Del. July 26, 2005) (striking plaintiff's willful infringement claim) (Sleet, J.) (Ex. 1).

Judge Sleet grounded his decision on the Federal Circuit's explicit, and controlling, holding that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004). The *Glaxo* court held that it was "clear legal error" to conclude that the "mere filing of an ANDA could form the basis of a willful infringement finding," adding that even a "wholly unjustified" paragraph IV certification in an ANDA filing, considered alone, is not enough to justify a finding of willful infringement. *Id.* District courts have uniformly applied *Glaxo* to strike or dismiss willful infringement claims based solely on the filing of an ANDA/paragraph IV certification. *See Allergan*, No. 04-0968 (Sleet, J.) (striking patentee's willful infringement claim from the complaint in paper NDA litigation); *Aventis Pharma Deutschland GmbH v. Cobalt Pharm.*, 355 F. Supp. 2d 586 (D. Mass. 2005) (granting Rule 12(c)

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[2] More than one company can be entitled to generic exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

[3] The Federal Circuit has expressly held that, pursuant to Rule 11, a patentee must ascertain the identity of the claims being asserted, what those claims mean, and why it believes that the claims are infringed *before* filing an infringement suit. *See View Eng'g v. Robotic Vision Sys.*, 208 F.3d 981, 984-86 (Fed. Cir. 2000).

motion for judgment on the pleadings dismissing claim for willful infringement in ANDA case); *Ortho-McNeil Pharm. v. Mylan Labs.*, No. 04-1689 (D.N.J. Apr. 18, 2005) (same) (Ex. 2).

Absent dismissal or having the claim stricken, Mylan will seek to bifurcate and stay discovery of Plaintiffs' baseless willfulness claim. Absent such relief, Mylan faces an impossible dilemma: waive privilege by asserting the advice-of-counsel defense to shield itself from a willfulness finding, or maintain privilege, thus risking an unwarranted willfulness finding. The Federal Circuit has recognized the dire consequences that a willfulness allegation has for the accused infringer, warning:

> An accused infringer . . . should not, without the trial court's careful consideration, be forced to choose between waiving the privilege in order to protect itself from a willfulness finding, in which case it may risk prejudicing itself on the question of liability, and maintaining the privilege, in which case it may risk being found to be a willful infringer if liability is found.

Quantum Corp. v. Tandon Corp., 940 F.2d 642, 643-44 (Fed. Cir. 1991). And given the Federal Circuit's rulings on this issue, bifurcation in patent cases "has become common." *Ciena Corp. v. Corvis Corp.*, 210 F.R.D. 519, 521 (D. Del. 2002). Indeed, since the *Quantum* decision, most district courts have bifurcated and stayed discovery on willfulness claims, particularly in ANDA litigation. *See, e.g., Eli Lilly & Co. v. Barr Labs.*, No. 02-1844, slip op. (S.D. Ind. Mar. 31, 2004) (bifurcating and staying discovery on willfulness in an ANDA case) (Ex. 3); *SmithKline Beecham Corp. v. Teva Pharms.*, No. 02-3779, slip op. (D.N.J. Mar. 7, 2003) (same) (Ex. 4); *Ortho-McNeil v. Teva Pharms.*, No. 02-2794, slip op. (D.N.J. Jan. 28, 2003) (same) (Ex. 5); *Allergan Inc. v. Pharmacia Corp.*, No. 01-141, 2002 WL 1268047, at *2 n.1 (D. Del. May 17, 2002) (same) (Ex. 6); *Pfizer Inc. v. Novopharm Ltd.*, 57 U.S.P.Q.2d 1442, 1445 (N.D. Ill. 2000) (same); *Eli Lilly & Co. v. Barr Labs.*, No. 96-0491, slip op. at 2-3 (S.D. Ind. Oct. 29, 1998) (same) (Ex. 7); *Bayer AG v. Barr Labs.*, No. 92-0381, slip op. at 1 (S.D.N.Y. Sept. 12, 1995) (same) (Ex. 8).[4]

Judicial economy and expediency, of particular importance in ANDA litigation, also weigh heavily in favor of bifurcation and the stay of discovery. Such relief, at a minimum,

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[4] *See also St. Clair Intellectual Prop. Consultants, Inc. v. Sony Corp.*, No. 01-557, 2002 WL 1901268, at *2 (D. Del. Aug. 16, 2002) (bifurcating and staying discovery on willfulness) (Ex. 9); *Arthrocare Corp. v. Smith & Nephew, Inc.*, No. 01-504, slip op. at 3 (D. Del. Nov. 27, 2002) (same) (Ex. 10); *Novopharm Ltd. v. TorPharm, Inc.*, 181 F.R.D. 308, 312 (E.D.N.C. 1998) (same); *Princeton Biochem., Inc. v. Beckman Instr., Inc.*, 180 F.R.D. 254, 256 (D.N.J. 1997) (same); *In re Recombinant DNA Tech. Patent & Contract Litig.*, 30 U.S.P.Q.2d 1881, 1900 (S.D. Ind. 1994) (same) *B. Braun Med. v. Abbott Labs.*, 32 U.S.P.Q.2d 1211, 1215-16 (E.D. Pa. 1994) (same).

postpones the disruptive discovery disputes and lengthy delays that inevitably accompany willfulness claims. *See Recombinant DNA*, 30 U.S.P.Q.2d at 1901 (bifurcating and staying willfulness discovery in part to minimize the use of valuable Court time by deferring issues concerning whether "particular documents are discoverable or protected by the attorney-client privilege"); *Rohm & Haas Co. v. Mobil Oil Corp.*, 654 F. Supp. 82, 86 (D. Del. 1987) ("If this Court grants [the motion to bifurcate], some potential conflicts, the resolution of which could require considerable efforts by the Court and parties, may be avoided or at least postponed" until after the liability phase of the trial, thereby promoting "economy, convenience, and expediency . . . ."), *aff'd without op.*, 895 F.2d 1421 (Fed. Cir. 1990).

Location of Depositions (Section 4(b)). Defendants seek nothing more than the default standard under the Federal Rules. Not so for Plaintiffs. While they voluntarily initiated this litigation, Plaintiffs nevertheless propose to force all witnesses to be deposed in their respective outside counsel's offices "unless the parties otherwise agree." Plaintiffs' proposal is absurd, and unsupported by the relevant case law. *See Topps Co. v. Productos Stani Sociedad Anomina Indus. y Commercial*, 2001 WL 406193, at *3-*4 (S.D.N.Y. Apr. 20, 2001) (requiring plaintiff to depose defendant's witness in Argentina, stating that "there is a presumption that the deposition of a defendant will take place at the location of the defendant's residence") (Ex. 11); *In Re Vivendi Universal, S.A. Sec. Litig.*, 2004 WL 3019766, at *1 (S.D.N.Y. Dec. 30, 2004) (requiring plaintiff depose defendant's witness in France, stating that "there is a general 'presumption that the deposition of a [witness] will take place at the location of the [witness'] residence'") (Ex. 12).

Few Defendants in the '318 Patent Litigation are located in the same State, let alone the same city, as their lead counsel. They should not be forced to travel hundreds, if not thousands, of miles for depositions merely because Plaintiffs do not wish to be inconvenienced. "[P]laintiff[s], having brought litigation and having exercised a choice as to where it would be conducted, cannot be heard to complain that a deposition is taking place in an inconvenient location." *Topps*, 2001 WL 406193, at *3. Plaintiffs' proposal should be rejected.

* * *

We look forwarding to meeting with the Court at the October 12, 2005 status conference.

Respectfully,

Mary B. Matterer

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